

STANDARD OPERATING PROCEDURE  
***PREPARING AND APPROVING PROTOCOLS***

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**KEY WORDS**

Formatting, study concept development, review panel

**APPROVALS**

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Environmental Monitoring Branch organization and personnel, such as management, quality assurance officer, project leader, etc., are defined and discussed in SOP [ADMN002.01](#).

The procedures for preparing and approving study memoranda and reports are outlined in SOP [ADMN007.00](#).

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**1.0 INTRODUCTION**

**1.1 Purpose**

This Standard Operating Procedure (SOP) provides guidance for preparing, reviewing, and approving protocols. Additional guidance is provided for studies conducted under Good Laboratory Practices (GLP) (U.S. EPA 40 CFR Part 160.120 and 160.185).

**1.2 Application**

Environmental Monitoring Branch management expects study staff to understand and apply the guidance provided by this SOP to all protocols, including contractual activities where DPR will be responsible for study documentation. If project staff cannot apply this guidance to their protocols for practical reasons, Branch management expects them to discuss and develop appropriate alternatives with their Project Supervisor.

The Branch Chief may authorize deviations from this SOP when:

- Emergency monitoring is needed.
- The target audiences for the protocol are not scientists.
- Requested by an external sponsor for studies conducted under grants, contracts, or other cooperative agreements.

**2.0 STUDY CONCEPT DEVELOPMENT**

**2.1 Purpose**

Establish a process that encourages project leaders to discuss a new study concept with key staff and management before developing the draft protocol. Management and key staff participation in concept discussions will:

- Ensure scientifically and statistically sound study design.
- Ensure concurrence with DPR or EM program goals.
- Identify potential obstacles to success (e.g., scientific, policy, resources).
- Reduce time required to complete protocol and report reviews.
- Develop a study team that may include staff beyond media-specific groups.
- Create a “library” of sound study concepts to allow longer-term program planning and quick response when unanticipated funding becomes available.

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### **2.2 Scope**

The Project Supervisor will determine when a study concept evaluation is required, or can be skipped and proceed with protocol development. In general, a study concept evaluation should be required for studies with:

- Unproven or unique study plan.
- New scientific concepts.
- Significant regulatory effect or media interest.

Project Supervisors and Project Leaders can use this process to evaluate and refine study concepts that do not meet the requirements listed above.

A study concept evaluation is not required for routine studies where the protocol is already established in an SOP or other documentation (e.g., 4-section surveys, well monitoring).

### **2.3 Participants**

Study team members (if already identified):

- Project Supervisor
- Project Leader
- Research Scientist, Senior Scientist, or Technical Adviser (protocols that include external peer review may not require a Research Scientist)
- Field Coordinator
- Laboratory Liaison
- Quality Assurance Officer
- Statistician

Optional but encouraged:

- One or more EM Research Scientists from beyond the media-specific group (as determined by Project Supervisor or Project Leader)
- External scientists or statisticians (e.g., other Branches, UC)
- Interested staff – selected based on current assignments, professional interest, or beneficial knowledge

**Note:** To ensure consistency throughout all phases of the proposed study, participants in the study concept development should expect to participate in the protocol and report review.

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### 2.4 Procedure

The Project Leader is responsible for initiating and following the procedure shown below:

Step	Action
1	Complete a literature review. <ul style="list-style-type: none"><li>• Required for the “concept development” phase for most studies.</li><li>• Exceptions would need to be identified by Research Scientist and management.</li></ul>
2	Discuss the study concept with Project Supervisor and obtain approval to initiate evaluation.
3	Prepare a brief concept paper. <ul style="list-style-type: none"><li>• Concept paper should include literature review discussion, project objectives, proposed study design, statistical analysis, and description of samples, laboratory analysis, and references.</li></ul>
4	Select evaluation participants. <ul style="list-style-type: none"><li>• Project Supervisor coordinates staff assignments with other supervisors.</li><li>• Evaluation participants may become the review panel for protocol and report reviews.</li></ul>
5	Schedule meeting to discuss concept and obtain feedback. <ul style="list-style-type: none"><li>• Distribute concept paper to participants with adequate time for review.</li></ul>
6	Collect, evaluate, and respond to participant feedback. <ul style="list-style-type: none"><li>• Discuss participant feedback and proposed responses with Project Supervisor</li><li>• Project Supervisor settles unresolved technical or policy issues.</li></ul>
7	Amend study concept as appropriate and obtain preliminary approval from Project Supervisor to proceed with protocol development <sup>1</sup> .

### 3.0 PROTOCOL DEVELOPMENT

#### 3.1 Overview

A protocol is a detailed plan of a scientific study<sup>2</sup>. The Environmental Monitoring Branch conducts studies to:

- Identify or characterize pesticide-related health or environmental problems.
- Develop measures to mitigate pesticide-related health or environmental problems.
- Assess the effectiveness of DPR’s regulatory program.

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<sup>1</sup> Approval at this phase does not guarantee project approval – could be delayed or cancelled due to unforeseen technical, resource, or management constraints.

<sup>2</sup> The American Heritage Dictionary, Second College Edition

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The Project Leader is responsible for protocol development and must ensure that the protocol has been approved through the review process described in [Section 4.0](#) before beginning the study or distributing the protocol to persons or organizations outside of DPR.

Project Leaders are encouraged to seek out expert assistance and advice from departmental Research Scientists, statisticians, or staff, or other external scientific authorities.

**3.2 Format and Content**

This section describes the standard protocol format and content for GLP and non-GLP studies. The Project Leader may elect to add other sections as appropriate. However, significant departures from this SOP must be discussed with the Project Supervisor in advance.

- 3.2.1 *Header* – Header content includes the department, branch and program name (if applicable), full address, and the date the protocol was approved. The text must be single-spaced, bolded, and centered. The DPR logo is optional, but if used should be placed in the top left corner.



**Department of Pesticide Regulation  
Environmental Monitoring Branch  
1001 I Street, PO Box 4015  
Sacramento, CA 95812**

**<Date>**

- 3.2.2 *Title* – The title should concisely describe the study and the text must be single-spaced, uppercase, bolded, and centered below the header.
- 3.2.3 *Sections* – Each section must be bolded, uppercase, and labeled with a Roman numeral and a heading listed in the table below:

<b>Section Heading</b>	<b>Study Type</b>	<b>Section Description</b>
<i>Introduction</i>	ALL	Provide a thorough explanation of the problem being addressed. Use relevant background information, factual data, and assessment to substantiate the nature, source, extent, or location of the problem.

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<b>Section Heading</b>	<b>Study Type</b>	<b>Section Description</b>
<i>Objective</i>	ALL	State the objective clearly and concisely. Identify the problem or hypothesis being addressed in the protocol.
<i>Personnel<sup>3</sup></i>	ALL	<p>Identify the personnel involved in the study using the following format:</p> <p>“The Environmental Monitoring Branch, under the overall supervision of (<i>Name</i>), Project Supervisor, will conduct this study. Other key personnel include:</p> <p>Project Leader – (<i>Name</i>)            Field Coordinator – (<i>Name</i>)            Research or Senior Scientist – (<i>Name</i>)            Statistician – (<i>Name</i>)            Quality Assurance/Laboratory Liaison – (<i>Name</i>)            Chemist – (<i>Name</i>) or Analytical Laboratory Supervisor – (<i>Name</i>)</p> <p>Please direct questions regarding this study to (<i>Name</i>), Contact Person, at (<i>phone number</i>) or (<i>e-mail address</i>). “</p> <p><b>Note:</b> Include project staff from other state, federal, county agencies, or private organizations in this section unless the study is conducted following GLP.</p> <p><b>Required for GLP studies:</b> List staff from other agencies or organizations under the section titled “Collaborators.”</p>
<i>Sponsor</i>	GLP	<p>Identify the project sponsor including:</p> <ul style="list-style-type: none"> <li>• Agency name and address</li> <li>• Contact name and phone number</li> </ul>
<i>Collaborators</i>	GLP	List names of collaborators, their agency/organizations, and addresses.
<i>Testing Facility and Personnel</i>	GLP	List all testing facility addresses such as the main office, warehouse, laboratory, and any satellite offices. The personnel part of this section follows the formatting procedure as described under the section titled <a href="#">Personnel</a> .
<i>Test Substances</i>	GLP	List the chemical names of the pesticides to be monitored or examined in the study.
<i>Test System Selection</i>	GLP	List matrices to be collected and sites to be examined as well as the justification for the selection of the matrices and sites.

<sup>3</sup> Responsibilities of key personnel are described in SOP ADMN002.01. Authorship of the final report may include but not limited to the personnel named above.

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<b>Section Heading</b>	<b>Study Type</b>	<b>Section Description</b>
<i>Study Plan</i>	ALL	<p>Explain the study design and methods that will be used to ensure that the objective is clearly measurable. This includes identifying:</p> <ul style="list-style-type: none"> <li>• Location of the study area.</li> <li>• Number of sites used in the study.</li> <li>• Media to be sampled.</li> <li>• Number of treatments and replications.</li> <li>• Sampling time intervals.</li> <li>• Number and type (field blank, lab QC, etc.) of samples collected.</li> <li>• Parameters to be measured in the study such as weather, water flow, water depth, pesticide deposition, treatment dates, etc.</li> <li>• If the study plan requires the application of pesticide(s) to study plots by DPR staff, contractors, cooperators, or licensed Pest Control Businesses, then the study plan must include a statement indicating that the Project Leader will notify the County Agricultural Commissioner and the appropriate Enforcement Branch Regional Office prior to conducting the pesticide application(s).</li> <li>• Other pertinent information as needed.</li> </ul> <p><b>Note:</b> Use tables, figures, and/or diagrams to aid readers in understanding the study design.</p>
<i>Sampling Methods/ Chemical Analytical Methods</i>	ALL	<p>Provide a detailed, sequential list of the activities that will be followed in the study including:</p> <ul style="list-style-type: none"> <li>• Procedures for collecting data such as:             <ul style="list-style-type: none"> <li>○ Sample collection</li> <li>○ Sample storage</li> <li>○ Equipment utilized</li> </ul> </li> <li>• A list of pesticides (test substances) to be analyzed and analytical methods to be used, sample storage and transport procedures, quality assurance and quality control measures.</li> <li>• Citations of relevant SOPs and analytical SOPs (methods).</li> <li>• <b>Required for GLP studies:</b> Attach all relevant SOPs to the protocol.</li> </ul>
<i>Data Analysis</i>	ALL	<p>Identify the proposed methods of statistical analysis to be used for each type of data collected (e.g., regression or ANOVA).</p>
<i>Timetable</i>	ALL	<p>Provide estimated dates (approximate month and year) for:</p> <ul style="list-style-type: none"> <li>• Field monitoring</li> <li>• Chemical analysis</li> <li>• Data analysis</li> <li>• Report preparation</li> <li>• Any other parameters not mentioned, but pertinent to the preparation and completion of the study</li> <li>• <b>Required for GLP studies:</b> Include experimental start and termination dates</li> </ul> <p><b>Note:</b> The time schedule should be reasonable and take into account risks (i.e., weather) and resource constraints (i.e., staffing changes).</p>

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<b>Section Heading</b>	<b>Study Type</b>	<b>Section Description</b>
<i>Records</i>	GLP	List the records that will be maintained and the location where the records will be kept. Citing that SOP <a href="#">ADMN005</a> will be followed for archiving is generally adequate.
<i>Budget</i>	Non-GLP Only	Estimate the cost of the study from the time of initiation to the time of completion. Include itemized expenses for: <ul style="list-style-type: none"> <li>• Personnel</li> <li>• Equipment and supplies</li> <li>• Travel</li> <li>• Laboratory costs</li> <li>• Other anticipated expenditures</li> </ul> List each expense and the approximate cost. Subtotal the dollar amounts for similarly grouped itemized costs and include a grand total amount for the study.
<i>Contract Information</i>	ALL	List information about any contracts or proposed contracts related to the study, including: <ul style="list-style-type: none"> <li>• Contract number</li> <li>• Contractor</li> <li>• Contract manager</li> <li>• Amount</li> <li>• Time period</li> <li>• Brief description of services to be provided</li> </ul>
<i>References</i>	ALL	Format references according to the guidelines in <a href="#">Publications Handbook &amp; Style Manual</a> and list them on a separate page. Include a reference and hyperlink to the approved study protocol.

3.2.4 *Signature Page (GLP Studies Only)* – Protocols must include the date of approval by the sponsor and the dated signature of the Project Leader (study director) prior to conducting the study.

**4.0 REVIEW AND APPROVAL PROCEDURES**

**4.1 Overview**

Prior to beginning a study all protocols must undergo a comprehensive review to ensure the appropriateness of the science, materials and methods, analytical methods, chemistry, quality assurance and control, statistics, policy, editorial accuracy, and any additional categories as needed. The review procedures are intended to provide staff with the opportunity to produce the best study possible and to utilize the available technical resources early in the project.



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In general, Project Supervisors and Project Leaders will follow normal chain-of-command (e.g., Program Supervisor, Branch Chief, Assistant Director) once they complete the review procedures outlined in this SOP for protocols. At each step, the management reviewer may return the document for revision, pass the document to the next management level, or give final approval.

The Project Supervisor should consult with management to determine which, if any, external entities (e.g., other agencies, universities, stakeholders) should review the protocol and whether the external review will occur before, concurrently, or after management review. If management requires external review, the Project Supervisor and/or Contact Person will coordinate the reviews and compose a cover letter that briefly describes the document and sets a deadline for comments. Depending on the timing and outcome of the external review, management may opt to conduct a second review. DPR policies or legal requirements may require additional review or supercede this SOP (e.g., scientific documents used to support rulemaking).

### **4.2 Purpose**

- Ensure that the proposed study design supports the study objectives.
- Identify significant technical or resource deficiencies that would constitute barriers to management approval.
- Develop solutions to deficiencies where possible.

### **4.3 Scope**

Required for all studies except routine studies where the protocol is already established in an SOP or other documentation (i.e., 4-section surveys, well monitoring).

### **4.4 Participants**

Minimum:

- Appropriate study team members
- Key staff who participated in the study concept development
- Program Supervisor and Branch Chief

Optional but encouraged:

- EM Research Scientists from beyond the media-specific group
- External scientists or statisticians (e.g., other Branches, UC)
- Interested staff – selected based on current assignments, professional interest, or beneficial knowledge

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**4.5 Procedure**

The Project Leader is responsible for initiating and following the review procedure shown below:

Step	Action
1	Provide the draft protocol to Project Supervisor for non-technical review.
2	Select the review panel participants. <ul style="list-style-type: none"> <li>• Project Supervisor coordinates staff assignments with other supervisors.</li> <li>• <b>Note:</b> If possible, the same panel participants should review the protocol, study memorandum (if produced) and report. Additional reviewers can be assigned as needed to address technical issues that arise throughout the study.</li> </ul>
3	Submit edited protocol to review panel with due date for written comments.
4	Evaluate panel's written comments with the Project Supervisor <sup>4</sup> and respond to comments in writing. <ul style="list-style-type: none"> <li>• Project Supervisor reviews comments for significant technical disagreements between panel members.</li> <li>• Program Supervisor or Branch Chief, in consultation with the Project Supervisor, will resolve significant technical disagreements between panel members or the panel and Project Leader before continuing the process.</li> <li>• <b>Required for GLP studies:</b> A copy of the reviews and responses must be included in the appendix.</li> </ul>
5	Revise the protocol according to panel's and Project Supervisor's comments. <ul style="list-style-type: none"> <li>• <i>For protocols with significant deficiencies:</i> Review process will be repeated until the panel and Project Supervisor approve the protocol.</li> <li>• Minor amendments will not require further technical review unless requested by panel members.</li> </ul>
6	Project Supervisor will submit approved draft protocol to Branch management for final approval. <ul style="list-style-type: none"> <li>• <i>Project Leader may not begin a study until management approves the study protocol.</i></li> </ul>
7	Obtains study number and send the numbered, approved protocol to the Branch webmaster for posting to DPR's websites.

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<sup>4</sup> The panel's comments, whether individual or group, will clearly identify significant technical deficiencies and minor amendments. Significant technical deficiencies are flaws in the study that are so great that, if uncorrected, would warrant management denial of the project.

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## **5.0 AMENDMENTS, REVISIONS, AND DEVIATIONS**

### **5.1 Amendments**

5.1.1 Whenever there are significant changes that occur **before** the study begins, a protocol amendment is required. Significant changes include:

- New project leader
- Major change in schedule such as conducting a study the following year
- Change in analytical screens and analytes
- Change in laboratory conducting analyses
- Changes in field sampling methods, plot design, and statistical analysis

5.1.2 The amendments may be formatted at the discretion of management. An official memorandum may be adequate.

5.1.3 Amendments must be approved following [Section 4.0](#) of this SOP.

5.1.4 **Note:** A new protocol must be written if the objective of the study changes in any way and a new study number should be requested.

### **5.2 Revisions**

5.2.1 Revisions are planned changes that occur **during** the study.

- The Project Leader must obtain the Project Supervisor's approval for the proposed revisions and must provide the revised protocol to all study participants before beginning the study.
- If the revision is scientifically significant (study design, statistical analysis, etc.), the Research Scientist, Senior Scientist, or Technical Advisor must also review and approve the proposed changes.
- Revisions may be made on the attached [Revision Log](#).

### **5.3 Deviations**

5.3.1 Deviations are unplanned changes that occur **during** the study.

- The Project Leader must document all deviations from an approved protocol, the reasons for the deviations, and the date.

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- The Project Leader must document all circumstances that may have affected the quality or integrity of the data.
- The possible consequences must be documented and maintained with the original protocol **and** reflected in the study memorandum or final report.

5.3.2 Deviations can be documented on the attached [Deviation Form](#).



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**DEVIATION FROM GOOD LABORATORY PRACTICES FORM**

Study Number & Name:

Date of Deviation:

Date Study Director/Project Leader Notified:

Protocol or SOP Affected:

Person(s) Making Deviation:

Description of Deviation:

Reason for Deviation:

Signature (person making report) \_\_\_\_\_ Date \_\_\_\_\_